

RECEIVED
CENTRAL FAX CENTER**AUG 16 2006****FAX TRANSMISSION****DATE:** August 16, 2006**PTO IDENTIFIER:** Application Number 09/674,457-Conf. #8539

Patent Number

Inventor: Per Andersson et al.**MESSAGE TO:** US Patent and Trademark Office**FAX NUMBER:** (571) 273-8300**FROM:** FULBRIGHT & JAWORSKI L.L.P.

Melissa W. Acosta 01768/10104200/GYROS

PHONE: (713) 651-5407**Attorney Dkt. #:** HO-P02191US0**PAGES (Including Cover Sheet):** 29**CONTENTS:**

Appeal Brief Transmittal (1 page)

One Month Request for Extension of Time Under 37 CFR 1.136(a) (1 page)

Appeal Brief (25 pages)

Charge \$120.00 to deposit account 06-2375

Certificate of Transmission (1 page)

If your receipt of this transmission is in error, please notify this firm immediately by collect call to sender at (713) 651-5407 and send the original transmission to us by return mail at the address below.

This transmission is intended for the sole use of the individual and entity to whom it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. You are hereby notified that any dissemination, distribution or duplication of this transmission by someone other than the intended addressee or its designated agent is strictly prohibited.

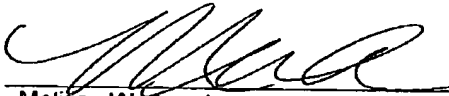
FULBRIGHT & JAWORSKI L.L.P.

Fulbright Tower, 1301 McKinney, Suite 5100, Houston, Texas 77010-3095

Telephone: (713) 651-5151 Facsimile: (713) 651-5246

RECEIVED
CENTRAL FAX CENTER

AUG 16 2006

TRANSMITTAL OF APPEAL BRIEF		Docket No. HO-P02191US0	
In re Application of: Per Andersson et al.			
Application No. 09/674,457-Conf. #8539	Filing Date May 7, 1999	Examiner D. K. Handy	Group Art Unit 1743
Invention: MICROFLUIDIC DEVICE			
<u>TO THE COMMISSIONER OF PATENTS:</u>			
Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed: <u>May 17, 2006</u>			
The fee for filing this Appeal Brief is _____ \$			
<input checked="" type="checkbox"/> Large Entity <input type="checkbox"/> Small Entity			
<input checked="" type="checkbox"/> A petition for extension of time is also enclosed.			
The fee for the extension of time is <u>\$ 120.00</u>			
<input type="checkbox"/> A check in the amount of _____ is enclosed.			
<input checked="" type="checkbox"/> Charge the amount of the fee to Deposit Account No. <u>06-2375</u> This sheet is submitted in duplicate.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. <u>06-2375</u> This sheet is submitted in duplicate.			
 Melissa W. Acosta Attorney Reg. No. : 45,872 FULBRIGHT & JAWORSKI L.L.P. Fulbright Tower 1301 McKinney, Suite 5100 Houston, Texas 77010-3095 (713) 651-5407		Dated: <u>August 16, 2006</u>	

25688107.1

RECEIVED
CENTRAL FAX CENTER

AUG 16 2006

Docket No.: HO-P02191US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Per Andersson et al.

Application No.: 09/674,457

Confirmation No.: 8539

Filed: May 7, 1999

Art Unit: 1743

For: MICROFLUIDIC DEVICE

Examiner: D. K. Handy

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within three months after the Notice of Appeal filed in this case on May 17, 2006, and is in furtherance of said Notice of Appeal. This submission is also accompanied with a Petition for Extension of Time of One Month and the requisite fee.

The fees required under § 41.20(b)(2) have been previously paid.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I.	REAL PARTY IN INTEREST.....	3
II.	RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS.....	3
III.	STATUS OF CLAIMS.....	3
	A. Total Number of Claims in Application	3
	B. Current Status of Claims.....	3
	C. Claims On Appeal.....	4
IV.	STATUS OF AMENDMENTS	4
V.	SUMMARY OF CLAIMED SUBJECT MATTER	4
VI.	GROUND OF OBJECTION TO BE REVIEWED ON APPEAL.....	5
	A. Whether claims 43 – 47 were properly rejected under 35 U.S.C. § 102(e) as anticipated by Kellogg, et al. (US6,143,248)	5
	B. Whether claims 43-47 were properly rejected under 35 U.S.C. § 102(a) as anticipated by Kellogg, et al. (WO9807019).....	5
	C. Whether claims 48-49 were properly rejected under 35 U.S.C. § 103(a) as rendered obvious by Kellogg, et al. (US6,143,248) or Kellogg, et al. (WO9807019).....	5
VII.	ARGUMENT.....	5
	A. Issues Under 35 U.S.C. § 102(e) Claim Rejections	5
	B. Issues Under 35 U.S.C. § 102(a) Claim Rejections	9
	C. Issues Under 35 U.S.C. § 103(a) Claim Rejections	9
VIII.	CLAIMS.....	10
IX.	EVIDENCE.....	11
X.	RELATED PROCEEDINGS	11
XI.	CONCLUSION	12
	APPENDIX A.....	13
	APPENDIX B.....	14

Application No.: 09/674,457

Docket No.: HO-P02191US0

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is the assignee, GYROS PATENT AB.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

Claims 1-19 were originally filed on January 5, 2001 in this case, which is the National Phase Application of PCT Application No. IB99/00907 filed May 7, 1999 claiming priority to United Kingdom patent application 9809943.5, filed on May 8, 1998.

B. Current Status of Claims

Claims 20 - 41 were added in a preliminary amendment dated July 25, 2002.

Following an Office Action mailed July 7, 2003, a response was filed on November 7, 2003 canceling claims 1 - 19, 21, 32, 34 - 35, and 37 - 40; amending claims 20 and 27 - 31; and adding claims 42 - 47.

A final Office Action was mailed on February 3, 2004 rejecting the outstanding claims 20 - 31, 33, 36 and 41 - 47. An RCE was filed August 3, 2004 canceling claims 29 and 30.

An Office Action mailed September 24, 2004, rejected the outstanding claims 20, 22 - 28, 31, 33, 36 and 41 - 47. A response was filed on February 22, 2005 canceling claims 20, 22 - 28, 31, 33, 36 and 41 - 42; amending claim 43; and adding claims 48 - 49.

A final Office Action was mailed on May 23, 2005 rejecting the outstanding claims 43 - 49.

Application No.: 09/674,457

Docket No.: HO-P02191US0

Applicant filed a Notice of Appeal on October 20, 2005 and a supporting Appeal Brief on December 20, 2005.

The Examiner reopened prosecution and issued an Office Action on March 9, 2006 again rejecting claims 43 – 49.

C. Claims On Appeal

The claims on appeal are claims 43 – 49.

IV. STATUS OF AMENDMENTS

Applicant filed a response with amendments on February 22, 2005. The Examiner's final Office Action mailed May 23, 2005 acknowledged entry of these amendments. No subsequent amendments are outstanding.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is a method of use for a co-disclosed circular microfluidic device (Figures 4-8). Specifically, it is a method of controlling the flow of a liquid sample in the device by way of intermittent regions of relatively hydrophobic and hydrophilic surfaces. (Page 3, lines 14-22; Page 6, lines 12-14; Figure 7: 14 and 15; Figure 8: Hydrophobic breaks A, B, C, and D). The fluid is placed into the device at an inlet. Generally, the fluid is a liquid which flows via capillary and/or centrifugal forces to a hydrophobic section within a predetermined hydrophilic pathway of the circular microfluidic apparatus. (Page 6, lines 12-16). The hydrophobic section prevents the aqueous solution from flowing further along the pathway. *Id.* Increased centrifugal force drives the aqueous solution through the hydrophobic section of the pathway allowing the fluid to continue to a distal portion of the microfluidic device. *Id.* Thus, these hydrophobic stop sections function as fluid valves to control the flow of samples between different parts of the hydrophilic pathway of the device.

Application No.: 09/674,457

Docket No.: HO-P02191US0

VI. GROUNDS OF OBJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 43 – 47 were properly rejected under 35 U.S.C. § 102(e) as anticipated by Kellogg, et al. (US6,143,248).**
- B. Whether claims 43-47 were properly rejected under 35 U.S.C. § 102(a) as anticipated by Kellogg, et al. (WO9807019).**
- C. Whether claims 48-49 were properly rejected under 35 U.S.C. § 103(a) as rendered obvious by Kellogg, et al. (US6,143,248) or Kellogg, et al. (WO9807019).**

VII. ARGUMENT**A. Issues Under 35 U.S.C. § 102(e) Claim Rejections**

Claims 43 – 47 are rejected under 35 U.S.C. § 102(e) over Kellogg et al. (6,143,248).

Anticipation of a claim is only established where “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

1. Claims 43-45 “the liquid flows down the hydrophilic pathway until the liquid reaches a hydrophobic section or valve in the pathway preventing the flow of liquid”

Claims 43-45 require hydrophilic pathways and a hydrophobic section within a hydrophilic pathway. The Examiner has previously acknowledged that Kellogg does not teach a hydrophobic section within a hydrophilic pathway in the Office Action dated 02/03/2004. Yet further, the Examiner has recently acknowledged in a related continuation application (USSN 11/302,713) that “Kellogg does not teach a hydrophobic section within a hydrophilic pathway to form a valve.” (See Office Action for USSN 11/302,713 dated 06/30/2006, page 4, 4th paragraph, Appendix B). The independent claims pending in USSN 11/302,713, as shown below, are broader than independent claim 43 on appeal.

A microfluidic device comprising:

a circular device which is adapted for rotation about its axis and comprises two substrates between which there are predetermined hydrophilic pathways

Application No.: 09/674,457

Docket No.: HO-P02191US0

for liquid flow, and a hydrophobic section within in a hydrophilic pathway to form a valve that provides a break in liquid flow passing through the pathway.

A method of producing a microfluidic device having the form of a disc which is adapted for rotation about an axis, and comprising two substrates at least one of which controls flow of a liquid in the microfluidic device comprising the step of:

treating at least one substrate such that the surface of the treated substrate comprises hydrophilic pathways for liquid flow of the liquid and and a hydrophobic section or valve within a hydrophilic pathway to prevent flow of the liquid.

A method for controlling flow of a liquid in a microfluidic device comprising the steps of:

providing a microfluidic device which is adapted for rotation about an axis and comprises two substrates between which there are predetermined hydrophilic pathways for liquid flow, and a hydrophobic section within a hydrophilic pathway to form a valve that provides a break in liquid flow passing through the pathway

adding the liquid to an inlet of the microfluidic device, wherein the liquid flows down the hydrophilic pathway until the liquid reaches the hydrophobic section or valve within the pathway preventing the flow of liquid; and

applying sufficient energy to the liquid allowing it to pass the valve and continue to flow down the pathway.

Thus, in view of the Examiner's most recent assessment of Kellogg, Appellants are led to believe that it is the opinion of the Examiner that Kellogg does not teach a hydrophobic section with a hydrophilic pathway to form a valve, and thus, Kellogg can not anticipate the claims on Appeal.

Regardless of the Examiner's paradoxical opinions of Kellogg, Appellants contend that the new passage (col. 10, lns 58 through col. 11, lns 54) cited by the Examiner relates to the embodiment of producing droplets, which is further described in columns 20 and 21 and illustrated in Figures 3A and 3B. Based upon this description in Kellogg, the passage

Application No.: 09/674,457

Docket No.: HO-P02191US0

referred to by the Examiner suggests that, if anything, both the reservoir and the microchannel connecting to it comprise the same surface modification-- both are hydrophobic. This does not teach a method of controlling flow of a liquid by using a hydrophobic section within a hydrophilic pathway in a microfluidic device. The flow of liquid or valving action in Kellogg depends upon reservoir and tube geometry (See col. 29, lns. 1-20; See also Figures 2 and 3 and the corresponding text, cols. 18-21). In addition to the geometries of the reservoir and tube or microchannel, the contact angles or surface modification of the reservoir and/or microchannel may contribute to the flow of liquid in the devices described by Kellogg. However, the contribution of contact angles of the surfaces is minor and not significant. (See col. 25 and 26, more specifically, col. 26, lns. 28-29 and equation 24). Thus, Kellogg may mention surface modification, however, one of ordinary skill in the art would have to pick and choose from the teachings of Kellogg in order to arrive at the claimed invention. Appellants submit that the issues at hand are akin to those of *In re Lemin* 141 U.S.P.Q. 815 (C.C.P.A. 1965). The court in *Lemin* determined that the selection of a compound from a known prior art genus, where that compound had selective and potent herbicidal action, rendered the compound special and significant, and therefore patentable over the prior art. There is nothing in the teaching of the Kellogg to indicate that fluid flow can be controlled by using merely a hydrophobic section within a hydrophilic pathway.

Kellogg also lacks written description for Appellant's claimed invention. Although surface modification is mentioned in the context controlling fluid flow, Kellogg focuses and provides working examples surface modification in combination with geometry changes. The court supports Appellants' position that Kellogg lacks written description and therefore is an improper 35 USC §102 reference. In *In re Petering* (49 CCPA 993; 301 F.2d 676; 1962 CCPA Lexis 285; 133 USPQ (BNA) 275), a genus disclosure in the prior art may anticipate a species claim only if the genus is so small that one of skill in the art would have immediately visualized every member of the genus. Kellogg provides no detailed description of controlling fluid flow by merely using a hydrophobic section within a hydrophilic pathway, so the skilled artisan would not have visualized using a hydrophobic section to control fluid flow.

Appellants, as well as the Examiner (See Office Action for USSN 11/302,713 dated 06/30/2006, page 4, 4th paragraph), contend that Kellogg does not teach the element of a

Application No.: 09/674,457

Docket No.: HO-P02191US0

hydrophobic section within a hydrophilic pathway. Thus, Kellogg et al. does not anticipate the claims on appeal.

2. Claims 43-45 "wherein the inlet is capable of handling less than about 500 nl"

Claims 43-45 incorporate the element "wherein the inlet is capable of handling less than about 500 nl."

The Examiner acknowledges that Kellogg et al. does not disclose use of nanoliter volumes. *See* Examiner's Final Rejection dated 05/23/05, section 4, lines 2-3. The Examiner and his Supervisor "did not *feel* that this excluded Kellogg from manipulating" volumes within the claim limit. (emphasis added). *Id.* at 3. Later, the Examiner asserted, "Examiner *believes* that an entry port 'having a volumetric capacity of 1 to about 100 (or 150) microliters is indeed capable of handling less than that amount.'" *Id.* pg 4, lines 5-7 (emphasis added). Based on feelings and beliefs, the Examiner demanded that Appellants prove that the entry port of the Kellogg et al. device cannot accommodate liquid sample volumes in the 500 nl or less range. *Id.* pg 3, lines 10-19. In the instant office action the Examiner restates this rejection to avoid the previous overtly subjective statements. *See* Examiner's Rejection dated 03/09/06, section 9. The substance of the rejection remains unchanged and is now expressly acknowledged to be based on inherency. *Id.*

"The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103." MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof). Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Application No.: 09/674,457

Docket No.: HO-P02191US0

The Examiner states that he “fails to see how Kellogg is not capable of handling the 500 nanoliter amount claimed by the Appellants.” See Examiner’s Rejection dated 03/09/06, section 9, last paragraph. This is not “a basis in fact and/or technical reasoning” supporting the argument that the inlet or entry port of the device disclosed in Kellogg et al. necessarily is capable of handling sample volumes of 500 nanoliter or less. Instead, the Examiner has required Appellants to *disprove* the inherent existence of a claim limitation in Kellogg et al “to overcome the previous rejection.” *Id.* The Examiner has not made a *prima facie* case that “wherein the inlet is capable of handling less than about 500 nl” is necessarily present in Kellogg et al. Hence, there is no valid rejection for the Appellants to overcome and the anticipation rejection relying on Kellogg et al. should be overruled.

3. Claims 46 and 47 “wherein the liquid has a surface tension > 18 mNm⁻¹” and “wherein the liquid is an aqueous solution or suspension having a surface tension > 50 mNm⁻¹”

The Examiner does not cite where in Kellogg these elements are disclosed. The Examiner does not discuss these limitations at all. The Examiner’s rejection is therefore procedurally and legally insufficient and should be overruled.

B. Issues Under 35 U.S.C. § 102(a) Claim Rejections

The Examiner’s 102(a) rejection is identical with the 102(e) rejection and should be overruled for the same reasons stated above.

C. Issues Under 35 U.S.C. § 103(a) Claim Rejections

“Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” MPEP § 2143.01.

1. Claim 48

Claim 48 requires that “the liquid sample comprises reagents.” The Examiner asserts, without identification of passages, that Kellogg discloses reagents in the reservoirs of the

Application No.: 09/674,457

Docket No.: HO-P02191US0

disclosed device. *See* Examiner's Rejection dated 03/09/06, section 7. Appellants agree that Kellogg contains this disclosure in Example 1.

The Examiner then argues that the claimed method is rendered obvious by Kellogg because "one would add them [the reagents] with the sample in order to allow for longer mixing times." This statements is comparable to the ones the *In re Lee* court rejected. 277 F.3d 1338, 1343 (Fed. Cir. 2002) (Conclusory statement that 'another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial' did not adequately address the issue of motivation to combine.). The Examiner's statements are also based on "subjective belief and unknown authority" rather than a reasoned and substantiated explanation of why one of skill in the art would be motivated to modify the cited reference. *Id.* at 1343-44. As such, the Examiner's statement is insufficient to establish a *prima facie* case and the rejection should be overruled.

2. Claim 49

Claim 49 requires that "the liquid sample is between 1 to 10nl." The Examiner cites no disclosure of sample volumes in this range. The Examiner does not explain how the device disclosed in Kellogg would teach or suggest the use of sample volumes in this range. Because the device in Kellogg is designed for processing samples in the volume range of 1-150 microliters, the Examiner's silence is understandable. *See* Examiner's Rejection dated 03/09/06, section 9. Undeterred, the Examiner asserts that "one would use smaller amounts of sample to conserve the sample material." *Id.* at section 7. As with the previous rejection, this is a conclusory and unsubstantiated statement on motivation to modify that cannot support a *prima facie* case of obviousness and should be overruled. *In re Lee* 277 F.3d at 1343-44.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A.

Application No.: 09/674,457

Docket No.: HO-P02191US0

IX. EVIDENCE

No evidence is submitted, hence no Appendix is included.

X. RELATED PROCEEDINGS

No related proceedings are referenced in II. above. No copies of decisions in related proceedings are not provided, hence no Appendix is included.

Application No.: 09/674,457

Docket No.: HO-P02191US0

XI. CONCLUSION

Appellants have provided arguments that overcome the pending rejections. Appellants respectfully submit that the Action's conclusions that the claims should be rejected are unwarranted. It is therefore requested that the Board overturn the rejection of the Action. Appellants respectfully request that the Board recommend that this application proceed to allowance.

Dated: August 16, 2006

Respectfully submitted,



By Melissa W. Acosta, Ph.D.

Registration No.: 45,872

FULBRIGHT & JAWORSKI L.L.P.

Fulbright Tower

1301 McKinney, Suite 5100

Houston, Texas 77010-3095

(713) 651-5151

(713) 651-5246 (Fax)

Agent for Applicant

Application No.: 09/674,457

Docket No.: HO-P02191US0

APPENDIX A**Claims Involved in the Appeal of Application Serial No. 09/674,457**

43. A method for controlling flow of a liquid in a microfluidic device comprising the steps of:

adding liquid to an inlet of a circular microfluidic device that is adapted for rotation about its axis, wherein said device comprises two substrates between which there are predetermined pathways for liquid flow, and wherein the inlet is capable of handling less than about 500nl of a liquid sample and the liquid flows down the hydrophilic pathway until the liquid reaches a hydrophobic section or valve in the pathway preventing the flow of liquid; and

applying sufficient energy to the liquid allowing it to pass the valve and continue to flow down the pathway.

44. The method of claim 43, wherein the liquid flows down the hydrophilic pathway to the valve by capillary action.

45. The method of claim 43, wherein the energy is centrifugal force created by rotating the device.

46. The method of claim 43, wherein the liquid has a surface tension $> 18 \text{ mNm}^{-1}$.

47. The method of claim 43, wherein the liquid is an aqueous solution or suspension having a surface tension $> 50 \text{ mNm}^{-1}$.

48. The method of claim 43, wherein the liquid sample comprises reagents.

49. The method of claim 43, wherein the liquid sample is between 1 to 10nl.

Application No.: 09/674,457

Docket No.: HO-P02191US0

APPENDIX B



UNITED STATES PATENT AND TRADEMARK OFFICE

AUG 16 2006

 UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/302,713	12/14/2005	Per Andersson	HO-P02191US1	2838
26271	7590	06/30/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			HANDY, DWAYNE K	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

 FULBRIGHT & JAWORSKI, LLP
 IPT DOCKETING
 Docketed ☒ Not Req'd ☐ Confirmation ☐
 Initials 1st JM Initials 2nd LJB

JUL 05 2006

Attorney

MWA - Gyros

Docket No.

P02191US1

Action Req'd

Date Due

Respond to OA

09/30/2006

Office Action Summary	Application No.		Applicant(s)	
	11/302,713		ANDERSSON ET AL	
	Examiner		Art Unit	
	Dwayne K. Handy		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/674,457.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/8/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Application/Control Number: 11/302,713

Page 2

Art Unit: 1743

DETAILED ACTION***Inventorship***

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Application/Control Number: 11/302,713

Page 3

Art Unit: 1743

3. Claims 20-34 and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) in view of Burns et al. (6,379,929). Kellogg teaches a microfluidic device comprised of circular disc having a microfluidic network. The micronetwork includes capillary microvalves to control fluid flow. This is described in column 15.

(13) Fluid (including reagents, samples and other liquid components) movement is controlled by centripetal acceleration due to rotation of the platform. The magnitude of centripetal acceleration required for fluid to flow at a rate and under a pressure appropriate for a particular microsystem is determined by factors including but not limited to the effective radius of the platform, the position angle of the structures on the platform with respect to the direction of rotation and the speed of rotation of the platform.

(14) The capillary microvalves of the invention is based on the use of rotationally-induced fluid pressure to overcome capillary forces. Fluids which completely or partially wet the material of the microchannels (or reservoirs, reaction chambers, detection chambers, etc.) which contain them experience a resistance to flow when moving from a microchannel of narrow cross-section to one of larger cross-section, while those fluids which do not wet these materials resist flowing from microchannels (or reservoirs, reaction chambers, detection chambers, etc.) of large cross-section to those with smaller cross-section. This capillary pressure varies inversely with the sizes of the two microchannels (or reservoirs, reaction chambers, detection chambers, etc., or combinations thereof), the surface tension of the fluid, **and the contact angle of the fluid on the material of the microchannels (or reservoirs, reaction chambers, detection chambers, etc.)**. Generally, the details of the cross-sectional shape are not important, but the dependence on cross-sectional dimension results in microchannels of dimension less than 500 .mu.m exhibit significant capillary pressure. By varying the intersection shapes, materials and cross-sectional areas of the components of the microsystems platform of the invention, "valve" are fashioned that require the application of a particular pressure on the fluid to induce fluid flow. This pressure is applied in the disks of the invention by rotation of the disk (which has been shown above to vary with the square of the rotational frequency, with the radial position and with the extent of the fluid in the radial direction). By varying capillary valve cross-sectional dimensions as well as the position and extent along the radial direction of the fluid handling components of the microsystem platforms of the invention, capillary valves are formed to release fluid flow in a rotation-dependent manner, using rotation rates of from 100 rpm to several thousand rpm. This arrangement allows complex, multistep fluid processes to be carried out using a pre-determined, monotonic increase in rotational rate.

Application/Control Number: 11/302,713
Art Unit: 1743

Page 4

Later, in column 29, Kellogg again notes the use of contact angle at the surface to control fluids.

(110) 2. Centrifugal rotors, microplatforms and Microsystems are also fabricated comprising material having contact angles $<90^\circ$ and other material having contact angles $>90^\circ$. For example, using aqueous solutions a fluid reservoir may be hydrophilic (contact angle $<90^\circ$), whereas a tube or channel is fabricated from a material having a contact angle $>90^\circ$. (thereby requiring positive pressure to be applied to motivate fluid flow from the reservoir into the channel).

Figure 9 shows how fluid is controlled when being passed through multiple channels and reservoirs. This process is described in column 28, lines 17-67. Kellogg shows embodiments with inlet ports and multiple pathways in Figures 11A-13. The embodiments of Figures 12 and 13 are described in Examples 2 and 3. Kellogg teaches treating the surface to adsorb biological fluid components in column 27, lines 15-18. Kellogg discloses a lid or cover and in col. 27, lines 42-58. Kellogg discloses the passing of water through the device in column 27, lines 59-67.

Kellogg does not teach a hydrophobic section within a hydrophilic pathway to form a valve. Burns et al. (6,379,929) teaches a chip based microfluidic device which also controls fluid flow in the channels through the use of areas of differing surface tensions. Burns discusses this in columns 7 and 8. Burns also shows an example in Figures 3A and 3B (described in columns 35 and 36). This embodiment of the device is described in column 35 and includes a hydrophobic region (40) which is used to stop fluid in the middle of a channel for flow control (column 8, lines 1-10). It would have been obvious to combine the hydrophobic patches from Burns with the device of Kellogg. Kellogg teaches an entire hydrophobic channel used to control fluid flow. The

Application/Control Number: 11/302,713
Art Unit: 1743

Page 5

use of only a region of hydrophobic material as taught by Burns would require less hydrophobic material in making the device. In addition, it would lessen the energy requirement for moving fluids across the region (Kellogg uses centripetal force) while still allowing for flow control.

4. Claims 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) and Burns et al. (6,379,929) in view of Sheppard, Jr. et al. (6,143,247). Kellogg and Burns, as described above in paragraph 3, teaches every element of claim 35 except for treating the substrate with plasma treatment. Sheppard also teaches a circular device for detecting and quantifying particulate matter suspended in a fluid. The invention provides an integrated, affinity-binding based, analytical system comprising a platform for performing an affinity-binding based assay for specifically binding particulates including microbial cells, and a detection means for detecting the particulates specifically bound to a defined surface or chamber comprising the platform. Methods for using the analytical systems of the invention are also provided. Sheppard teaches surface modification through plasma deposition in column 16, lines 9-37, including the use of materials that will attract and bind cellular material. It would have been obvious to one of ordinary skill in the art to combine the plasma coating of the cell affinity material of Sheppard with the method of Kellogg and Burns. One would use the plasma coating method since it is a well-known substrate coating method which can be used to coat the cellular affinity materials of Sheppard onto a substrate.

Application/Control Number: 11/302,713
Art Unit: 1743

Page 6


Conclusion

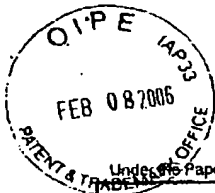
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
June 21, 2006


Jill Warden
Supervisory Patent Examiner
Technology Center 1700



PTO/SB/08A (10-01)
 Approved for use through 10/31/2002 OMB 0651-0031
 U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE
 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	11/302,713
		Filing Date	December 14, 2005
		First Named Inventor	Per Andersson
		An Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet	1	of	4
		Attorney Docket Number	HO-P02191US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
DKM	A1	US-2002-0025583	02-28-2002	Ellsworth et al.	
	A2	US-2002-0125135	09-12-2002	Larsson et al.	
	A3	US-2002-0150512-A1	10-17-2002	Kellogg et al.	
	A4	US-2003-0029724	02-13-2003	Derand et al.	
	A5	US-2003-0053934-A1	03-20-2003	Andersson et al.	
	A6	US-2003-0054563-A1	03-20-2003	Ljungstrom et al.	
	A7	US-2003-0064004	04-03-2003	Agren et al.	
	A8	US-2003-0066959	04-10-2003	Andersson et al.	
	A9	US-2003-0082075-A1	05-01-2003	Agren et al.	
	A10	US-2003-0129360-A1	07-10-2003	Derand et al.	
	A11	US-2003-0156763-A1	08-21-2003	Soderman	
	A12	US-2003-0173650	09-18-2003	Larsson et al.	
	A13	US-2003-0211012-A1	11-13-2003	Bergstrom et al.	
	A14	US-2003-0143114	07-31-2003	Andersson et al.	
	A15	US-2004-0055136	03-25-2004	Ohman et al.	
	A16	US-2004-0058408-A1	03-25-2004	Thomas et al.	
	A17	US-2004-0096867-A1	05-20-2004	Andersson et al.	
	A18	US-2004-0099310-A1	05-27-2004	Andersson et al.	
	A19	US-2004-0120856-A1	06-24-2004	Andersson et al.	
	A20	US-2004-0202579	10-14-2004	Derand et al.	
	A21	US-2005-0042770	02-24-2005	Derand et al.	
	A22	US-2005-0129800	06-16-2005	Ohman et al.	
	A23	US-2005-0141344	08-30-2005	Ekstrand et al.	
	A24	US-2005-0153431	07-14-2005	Andersson et al.	
	A25	US-2005-0153432	07-14-2005	Andersson et al.	
	A26	US-2005-0153433	07-14-2005	Andersson et al.	
	A27	US-2005-0153434	07-14-2005	Andersson et al.	
	A28	US-2005-0179901	08-18-2005	Ostlin et al.	
	A29	US-2005-0186685	08-25-2005	Kange et al.	
	A30	US-2005-0202471	09-15-2005	Tooke et al.	
	A31	US-2005-0214442	09-29-2005	Larsson et al.	
	A32	US-2005-0277195	12-15-2005	Holmquist et al.	
	A33	US-2005-0279925	12-22-2005	Andersson et al.	
	A34	US-2006-0002825	01-05-2006	Derand et al.	
	A35	US-3,679,367	07-25-1972	Negersmith	
	A36	US-4,018,652	04-19-1977	Lanham et al.	
	A37	US-4,077,845	03-07-1978	Johnson	
	A38	US-4,154,793	05-15-1979	Guigan	
	A39	US-4,318,994	03-09-1982	Meyer et al.	
	A40	US-4,381,291	04-26-1983	Ekins, et al.	
	A41	US-4,426,451	01-17-1984	Columbus	
	A42	US-4,440,838	04-03-1984	Millard et al.	
	A43	US-4,515,889	05-07-1985	Klose et al.	
	A44	US-4,661,451	04-28-1987	Hansen	
DKM	A45	US-4,676,274	06-30-1987	Brown	

Examiner Signature 25622770	<i>Raymond K Hardy</i>	Date Considered	6/20/06
--------------------------------	------------------------	-----------------	---------

PTO/SB/08A (10-01)

Approved for use through 10/31/2002 OMB 0651-0031

U. S. Patent and Trademark Office: U. S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	11/302,713
		Filing Date	December 14, 2005
		First Named Inventor	Per Andersson
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet	2	of	4
		Attorney Docket Number	HO-P02191US1

101	A46	US-4,676,952	06-30-1987	Edelmann et al.	
	A47	US-4,729,862	03-08-1988	Salatiello et al.	
	A48	US-4,745,072	05-17-1988	Ekins et al.	
	A49	US-4,756,884	07-12-1988	Hillman et al.	
	A50	US-4,762,683	08-09-1988	Romanauskas	
	A51	US-4,868,129	09-19-1989	Gibbons et al.	
	A52	US-4,917,865	04-17-1990	Romanauskas	
	A53	US-4,940,527	07-10-1990	Kazlauskas et al.	
	A54	US-4,946,795	08-07-1990	Gibbons et al.	
	A55	US-5,006,749	04-09-1991	White	
	A56	US-5,122,284	06-19-1992	Brayn et al.	
	A57	US-5,160,702	11-03-1992	Kopf-Sill et al.	
	A58	US-5,171,695	12-15-1992	Ekins	
	A59	US-5,173,262	12-22-1992	Burtis et al.	
	A60	US-5,230,866	07-27-1993	Shartle et al.	
	A61	US-5,242,803	09-07-1993	Burtis et al.	
	A62	US-5,252,294	10-12-1993	Kroy et al.	
	A63	US-5,304,487	04-19-1994	Wilding et al.	
	A64	US-5,368,704	11-29-1994	Madou et al.	
	A65	US-5,376,252	12-27-1994	Eksstrom et al.	
	A66	US-5,409,665	04-25-1995	Burd	
	A67	US-5,413,732	05-09-1995	Buhl et al.	
	A68	US-5,426,032	06-20-1995	Phillips et al.	
	A69	US-5,432,009	07-11-1995	Tabata et al.	
	A70	US-5,472,603	12-05-1995	Schembri	
	A71	US-5,587,128	12-24-1996	Wilding et al.	
	A72	US-5,593,838	01-14-1997	Zanzucchi et al.	
	A73	US-5,627,041	05-06-1997	Shartle	
	A74	US-5,635,358	06-03-1997	Wilding et al.	
	A75	US-5,650,334	07-22-1997	Zuk et al.	
	A76	US-5,653,939	08-05-1997	Hollis et al.	
	A77	US-5,660,993	08-26-1997	Cathey et al.	
	A78	US-5,690,841	11-26-1997	Elderliq	
	A79	US-5,698,162	12-16-1997	Belly et al.	
	A80	US-5,773,488	06-30-1998	Allmer et al.	
	A81	US-5,798,215	08-25-1998	Cathey et al.	
	A82	US-5,912,134	06-15-1999	Shartle	
	A83	US-5,962,081	10-05-1999	Ohman et al.	
	A84	US-5,992,820	11-30-1999	Fare et al.	
	A85	US-5,995,209	11-30-1999	Ohman et al.	
	A86	US-6,074,827	06-13-2000	Nelson et al.	
	A87	US-6,126,765	10-03-2000	Ohman et al.	
	A88	US-6,130,098	10-10-2000	Handique et al.	
	A89	US-6,143,247	11-07-2000	Sheppard, Jr. et al.	
	A90	US-6,143,248	11-07-2000	Kellogg et al.	
	A91	US-6,144,447	11-07-2000	Ohman et al.	
	A92	US-6,192,768	02-27-2001	Wallman	
	A93	US-6,203,291	03-20-2001	Stemme et al.	
DEA	A94	US-6,271,040	08-07-2001	Buechler	

Examiner Signature 2562770	<i>Dwayne K. Hanley</i>	Date Considered	6/28/06
----------------------------------	-------------------------	--------------------	---------

PTO/SB/08A (10-01)

Approved for use through 10/31/2002 OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
		Application Number	11/302,713
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	December 14, 2005
		First Named Inventor	Per Andersson
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet	3	of	4
		Attorney Docket Number	HO-P02191US1

Den	A95	US-6,296,020	10-02-2001	McNeely et al.	
	A96	US-6,299,839	10-09-2001	Karunaratne et al.	
	A97	US-6,319,468-B1	11-20-2001	Sheppard, Jr. et al.	
	A98	US-6,319,469-B1	11-20-2001	Mian et al.	
	A99	US-6,322,682	11-27-2001	Arvidsson et al.	
	A100	US-6,379,929	04-30-2002	Burns et al.	
	A101	US-6,454,970	09-24-2002	Ohman et al.	
	A102	US-6,499,499	12-31-2002	Dantsker et al.	
	A103	US-6,591,852	07-15-2003	McNeely et al.	
	A104	US-6,620,478	09-18-2003	Ohman et al.	
	A105	US-6,632,656	10-14-2003	Thomas	
	A106	US-6,637,469	06-10-1997	Wilding et al.	
	A107	US-6,653,625-A1	11-25-2003	Andersson et al.	
	A108	US-6,717,136-A1	04-08-2004	Andersson et al.	
	A109	US-6,728,644-A1	04-27-2004	Bielik et al.	
	A110	US-6,811,736	11-02-2004	Ohman et al.	
	A111	US-6,812,456-A1	11-02-2004	Andersson et al.	
	A112	US-6,812,457-A1	01-29-2004	Andersson et al.	
	A113	US-6,852,851	02-08-2005	Kenrick et al.	
	A114	US-6,878,555-A1	04-12-2005	Andersson et al.	
	A115	US-6,884,370-A1	04-26-2005	Ohman et al.	
	A116	US-6,884,395	04-26-2005	Andersson et al.	
	A117	US-6,919,058-A1	07-19-2005	Andersson et al.	
	A118	US-6,955,738-A1	10-18-2005	Derand et al.	
	A119	US-6,967,101	11-22-2005	Larsson et al.	
	A120	US-6,985,672	01-10-2006	Andersson et al.	
	A121	US-6,985,672	01-24-2006	Andersson et al.	